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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,813	10/19/2004	Johannes Coy	4007.008	6538

41288 7590 10/08/2008

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,813	COY, JOHANNES	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-39,41-51,54,57,58 and 61-70* is/are pending in the application.

4a) Of the above claim(s) *39,41-43,51,54,57,58 and 61-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-38,44-50 and 65-70* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/18/08 has been entered.

Claims 34-39, 41-51, 54, 57, 58, 61-70 are pending.

Claims 39, 41-43, 51, 54, 57, 58, and 61-64 are withdrawn.

Claims 34, 44, and 47-50 have been amended by Applicant.

Claims 34-38, 44-50, and 65-70 are currently under consideration.

This Office Action contains New Rejections necessitated by amendments.

Rejections Withdrawn

All previous rejections are withdrawn.

New Objections

Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 44 recites: “The method according to claim 34, wherein step (b) comprises using at least one nucleic acid probe, that hybridizes under stringent conditions to SEQ ID NO:1".

Because claim 34 requires use of said probe (see independent claim 1), claim 44 does not further limit claim 34. Proper correction is required.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-38, 44-50, and 65-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method for detecting carcinoma tissue in an individual comprising detecting in a tissue sample obtained from said individual the level of polynucleotides comprising SEQ ID NO:1 and comparing said level to the level of polynucleotides comprising SEQ ID NO:1 in a corresponding control tissue sample from a healthy subject, wherein a higher level of polynucleotides comprising SEQ ID NO:1 in the tissue sample from the individual as compared to said control tissue sample indicates that the tissue sample from the individual comprises carcinoma tissue, **does not reasonably provide enablement for** an in vitro method for detecting every type of disorder characterized by abnormal cell proliferation in an individual comprising detecting in just any biological sample obtained from said individual and just any normal control sample a level of polynucleotides that hybridize to a probe that is at least 80% identical to a part of at least 15 consecutive nucleotides of SEQ ID NO:1 or is complementary or reverse complementary to such a

part and wherein said probe hybridizes under stringent conditions to SEQ ID NO:1 but does not hybridize to an other transketolase or transketolase like sequence, wherein a higher level of detected polynucleotides in the biological test sample as compared to the level of detected polynucleotides in the normal control samples indicates that said individual has at least one of any disorder characterized by abnormal cell proliferation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant claims are drawn to an in vitro method for detecting every type of disorder characterized by abnormal cell proliferation in an individual comprising detecting in just any biological sample obtained from said individual and just any normal control sample a level of polynucleotides that hybridize to a probe that is at least 80% identical to a part of at least 15 consecutive nucleotides of SEQ ID NO:1 or is complementary or reverse complementary to such a part and wherein said probe hybridizes under stringent conditions to SEQ ID NO:1 but does not hybridize to an other

transketolase or transketolase like sequence, wherein a higher level of detected polynucleotides in the biological test sample as compared to the level of detected polynucleotides in the normal control samples indicates that said individual has at least one of any disorder characterized by abnormal cell proliferation. This includes methods wherein just any samples are used and methods wherein every disorder characterized by abnormal cell proliferation, including those characterized by having either increased or decreased proliferation, is detected.

This invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology". Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The specification teaches an in vitro method for detecting carcinoma tissue in an individual comprising detecting in a tissue sample obtained from said individual the level of polynucleotides comprising SEQ ID NO:1 and comparing said level to the level of polynucleotides comprising SEQ ID NO:1 in a corresponding control tissue sample from a healthy subject, wherein a higher level of polynucleotides comprising SEQ ID NO:1 in the tissue sample from the individual as compared to said control tissue sample indicates that the tissue sample from the individual comprises carcinoma tissue (see Example 2, in particular). Carcinomas disclosed as overexpressing polynucleotides comprising SEQ ID NO:1 include those of colon, lung and stomach (see Example 2). However, the specification does not demonstrate that polynucleotides comprising SEQ ID NO:1 are overexpressed in tissue from a patient with a carcinoma other than the carcinoma tissue. Further, the specification does not demonstrate that polynucleotides

comprising SEQ ID NO:1 are overexpressed in any disorders characterized by abnormal cell proliferation other than carcinomas. Disorders characterized by abnormal cell proliferation include pre-neoplasia, glomerulonephritis, benign prostate hyperplasia, and psoriasis. Further, the specification does not demonstrate that polynucleotides comprising SEQ ID NO:1 functionally regulate proliferation.

The level of unpredictability for the detection of any disorder based on expression of a particular marker is quite high. The state of the prior art dictates that one would not predict that a particular expression pattern of a particular marker is indicative of a particular disorder without demonstrating said particular expression pattern correlates with said disorder. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Therefore, absent evidence of a particular expression pattern of a particular marker correlating to a particular disorder, one of skill in the art would not predict that said particular expression pattern is indicative of said particular disorder without undue experimentation.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to an in vitro method for detecting every type of disorder characterized by abnormal cell proliferation in an individual comprising

detecting in just any biological sample obtained from said individual and just any normal control sample a level of polynucleotides that hybridize to a probe that is at least 80% identical to a part of at least 15 consecutive nucleotides of SEQ ID NO:1 or is complementary or reverse complementary to such a part and wherein said probe hybridizes under stringent conditions to SEQ ID NO:1 but does not hybridize to an other transketolase or transketolase like sequence, wherein a higher level of detected polynucleotides in the biological test sample as compared to the level of detected polynucleotides in the normal control samples indicates that said individual has at least one of any disorder characterized by abnormal cell proliferation, and Applicant has not enabled said method because it has not been shown that a higher level of detected polynucleotides that hybridize to a probe that is at least 80% identical to a part of at least 15 consecutive nucleotides of SEQ ID NO:1 or is complementary or reverse complementary to such a part and wherein said probe hybridizes under stringent conditions to SEQ ID NO:1 but does not hybridize to an other transketolase or transketolase like sequence in just any sample from an individual as compared to the level of detected polynucleotides that hybridize to a probe that is at least 80% identical to a part of at least 15 consecutive nucleotides of SEQ ID NO:1 or is complementary or reverse complementary to such a part and wherein said probe hybridizes under stringent conditions to SEQ ID NO:1 but does not hybridize to an other transketolase or transketolase like sequence in just any control sample is indicative of every disorder characterized by abnormal cell proliferation.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642